



# IAP GUIDE BOOK ON IMMUNISATION



COMMITTEE ON IMMUNISATION  
INDIAN ACADEMY OF PEDIATRICS

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# **IAP GUIDE BOOK ON IMMUNISATION**

**GUIDELINES FOR PRACTITIONERS  
ON IMMUNISATION**



**COMMITTEE ON IMMUNISATION  
INDIAN ACADEMY OF PEDIATRICS**

**1996**



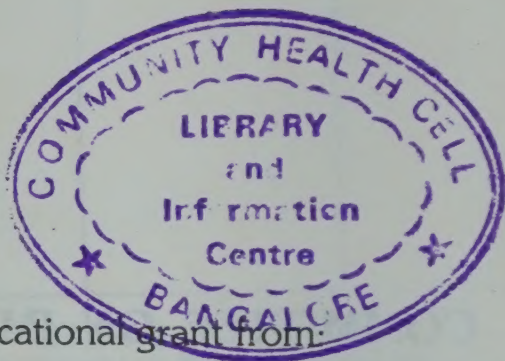
**First Edition**  
**September 1996**  
**Revised**  
**December 1996**  
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**Editors : Dr. T. Jacob John**  
**Dr. A. Parthasarathy**  
**Dr. Swati Y. Bhawe**

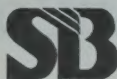
***Address for Correspondence :***

**Hony. General Secretary,**  
**Indian Academy of Pediatrics,**  
**"Kailash Darshan" Building,**  
**Kennedy Bridge,**  
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## FOREWORD

Over the past few years the efforts to control vaccine preventable diseases have gained a fresh strong momentum. Continued and concerted endeavours along with an increase in general awareness among people are very likely to lead to eradication of poliomyelitis by the year 2000 and a vastly improved vaccination coverage against other common conditions. Control of diseases against which effective vaccines have only recently become available, is now an emerging priority.

Pediatricians and other health personnel must keep their knowledge updated in various aspects of recent developments as well as in the current policies and practices of immunisation. At times they are faced with diverse opinions and conflicting advice and need to consult an authoritative text.

The present guide gives state-of-the art information on various aspects and issues concerning immunisation in a clear and concise manner. It should serve as a tool of learning and instruction. I am sure it will be found useful by our members.

On behalf of the Indian Academy of Pediatrics, I thank M/s. SmithKline Beecham for the publication of this Guide.

**Dr. R. N. SRIVASTAVA**

*President*

*Indian Academy of Pediatrics 1996.*

## PREFACE

Immunisation is the major success story of Public Health of the 20th Century. There are 3 components to this achievement, namely the eradication of small pox, the routine immunisation of 80-90% of all infants born anywhere in the world with the core vaccines of the Expanded Programme on Immunisation and the development and introduction of several, excellent, newer vaccines. There is a potential fourth component, no less significant than any other, namely the drive towards global eradication of poliomyelitis. We may achieve success before, or by, the year 2000, or perhaps in the early 21st century. However we can be proud of this, our gift, to the infants born in the next century, nay, millennium.

Immunisation represents the best of high technology brought down to the level of a few easily administered doses, by injection or by mouth. We pediatricians are part of this global mission, and we participate in it in the best tradition of our care and carefulness for the health and well-being of children everywhere. We must, therefore, not only follow the time-tables and schedules, but also learn the principles behind the practices. Parents, wishing the best for their children, may be misguided and reluctant to immunise; we have to counsel them. They may be worried or anxious before or after injections, particularly in case of some adverse reactions; we have to counsel them. Many children may not go through the recommended time table. Their parents will have many questions; we have to counsel them and catch up with the child's immunisation. All these demands are on us, pediatricians.

It is for these reasons that we dedicate this guide book to the children whom we serve. It is my hope that all pediatricians will study the contents carefully.

**Dr. T. JACOB JOHN**

*Chairman*

*IAP Committee on Immunisation 1994-'96*



## PROLOGUE

A long cherished dream of IAP has since materialised. A standard "IAP Immunisation and Health Record" and a set of "Teaching slides on Immunisation" for the benefit of faculty members and post graduates in Pediatrics as well as for the practicing pediatricians and a "Guide Book on Immunisation" which will serve as a table top reference were the felt needs of the IAP for a long time.

A sub-committee of IAP entitled "IAP committee on immunisation" was first formed in 1986 with the then president Dr. N. Sundaravali as chairperson, Dr. A. Parthasarathy as convenor and Dr. T. Jacob John as adviser. The committee was entrusted with the specific tasks of defining the number of primary doses for Oral Polio Vaccine, incorporating the Measles vaccine in the then EPI schedule and advancing the age for first primary dose of DPT vaccine. In a modest way the committee recommended 5 primary doses for OPV at birth, 6, 10, 14 weeks and 9 months; 3 primary doses for DPT at 6, 10, 14 weeks instead of at 3, 4, 5 months and one dose for Measles vaccine at 9 months followed by one booster dose for DPT and OPV at 18-24 months, which WHO accepted.

Subsequently to orientate the members on the Universal Immunisation Programme (UIP), Dr. Raju C. Shah took over as National Co-ordinator in 1987 under the stewardship of Dr. R.D. Potdar. Several State Co-ordinators were appointed, standard set of slides were prepared along with a reference book and countrywide orientation workshops were conducted in 1987-88 with assistance from the Government of India and UNICEF.

To consolidate the efforts of IAP, in the field of immunisation, a regular sub-committee on immunisation was formed in 1989, under the chairmanship of Dr. Mrs. A.B. Desai with Dr. Raju C. Shah as convenor and Dr. Vijay Agarwal, Dr. Ashok Dutta, Dr. S.K. Mittal and Dr. A. Parthasarathy as members along with the respective Presidents and Secretaries as ex-officio members. This committee popularised the concepts in Pediatric immunisation and



also brought out informative publications, conducted several update meets throughout the country and ultimately came out with a reference volume the "Blue Book of IAP" entitled "Immunity, Immunisation and Infectious Diseases". This marked a great era of academic achievement.

The present committee took over in 1994 with Dr. T. Jacob John as chairman, Dr.A. Parthasarathy as convenor and Dr. S.R. Banerjee, Dr. M. Indrashekhar Rao, Dr. M. Nagaraja Rao, Dr. N. Shendurnikar, Dr. H.P.S. Sachdev and Dr. Tapan Kumar Ghosh as members with Dr. Raju C. Shah, Dr. M.R. Lokeshwar, Dr. Swathi Y. Bhawe, Dr. R.N. Srivastava and Dr. Y.K. Amdekar as ex-officio members. As a first task the committee initiated the introduction of a new section in Indian Pediatrics entitled "Immunisation dialogue" and also articles on immunisation in the IAP Journal of Practical Pediatrics which proved to be very popular. Simultaneously several immunisation update meets were conducted throughout the country with active participation of IAPCOI members.

The present effort is to consolidate the contributions made by the Committees on Immunisation from 1986 onwards and organise IAP Jenner Symposia on Immunisation throughout the country. With a decade of dedicated work by a team of experts the present addition to the existing armamentarium of academic material on immunisation is presented to you. You are requested to go through the contents carefully and indicate your further needs to the undersigned so that we can incorporate more details in future editions. We are confident that the guidelines presented in this Guide Book will serve as a table top reference both for the faculty cum postgraduates and the practitioners. On this memorable occasion we acknowledge with gratitude the guidance from our past and present presidents and the financial help rendered by M/s. SmithKline Beecham Pharmaceuticals (I) Ltd., Bangalore.

**Dr. SWATI Y. BHAVE**

National Co-ordinator  
Jenner Symposia  
Hony. General Secretary  
IAP 1996-97

**Dr. A. PARTHASARATHY**

Convenor IAP COI 1994-96  
President - IAP 1997

## ACKNOWLEDGEMENT

Indian Academy of Pediatrics would like to place on record its grateful thanks to the following dedicated staff of M/s. SmithKline Beecham Pharmaceuticals (I) Ltd., Madras Zonal Office for their secretarial assistance and devoted service rendered in connection with the preparation of the hard copies of the slide materials and the contents of the Guide Book : Messrs. P.K. Ramanathan, P. V. Chandra Sekar, M. Narayanasamy and K.B.S. Menon. Our overall appreciation and gratitude to Mr. N. Manjunath, Product Manager, Bangalore and his office staff for assistance rendered from time to time, especially in the preparation of IAP Immunisation and Health Record.

IAP also gratefully acknowledges the timely help rendered by M/s. Alamu Printing Works, Chennai-14 for their prompt delivery of this Guide Book on time, despite very short notice. Our special thanks go to Mr. D. Ramanathan, Mrs. Mary Bernad and Selvi S. Parameswari and to the innumerable helping hands which enabled this publication to see the light of the day.

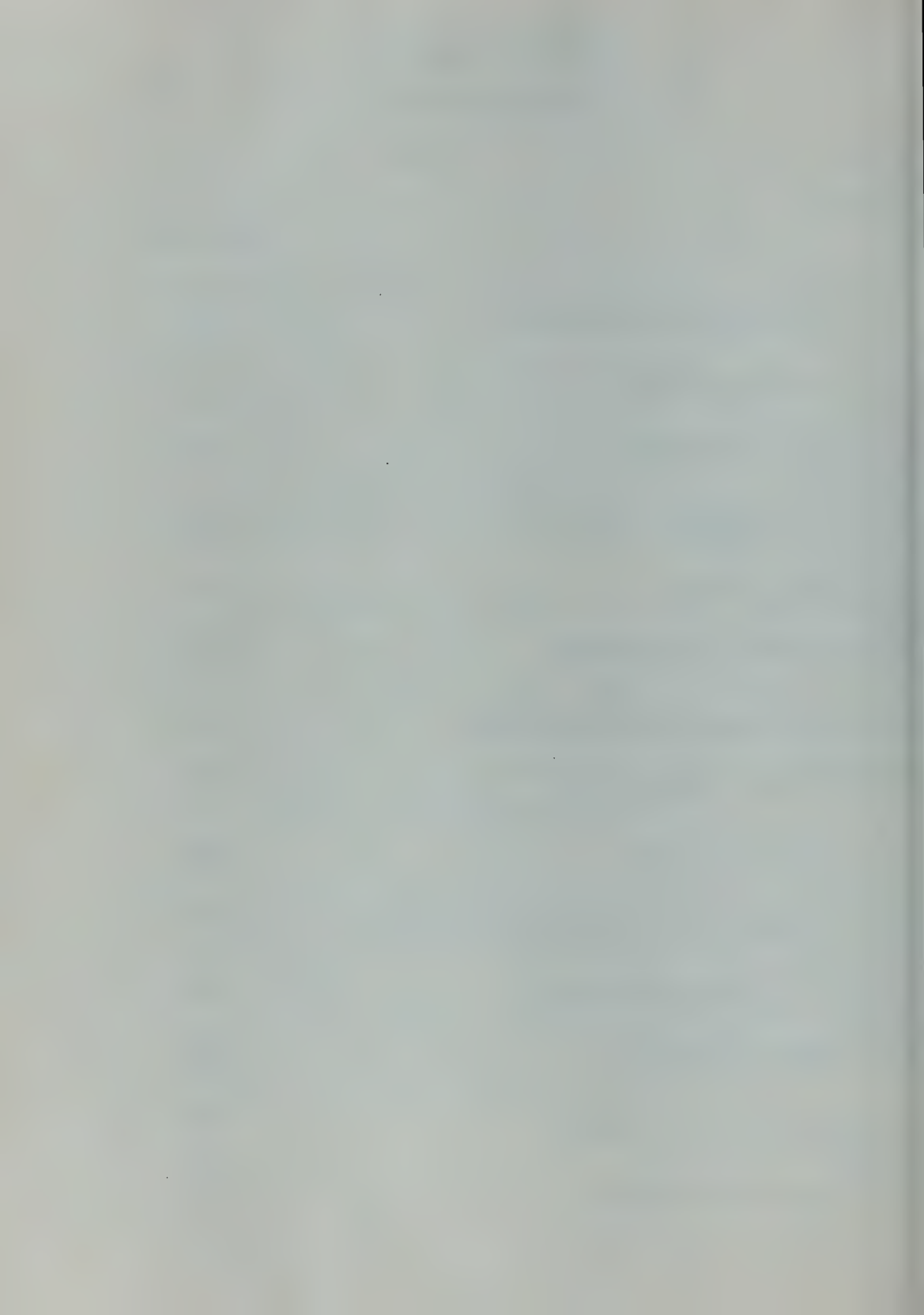
Our thanks are also due to the office bearers and members of IAP Committee on Immunisation and the members of the IAP publication Committee for the pains they have taken to go through the hard copies of the slide material, contents of the Guide Book and the IAP Immunisation and Health record and offering valuable suggestions which helped us to enrich the contents of the Guide Book.

- Editors



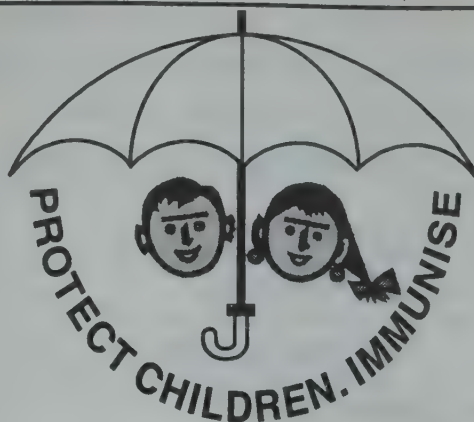
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## PROTECT CHILDREN. IMMUNISE



Protection from preventable diseases, disabilities and death through immunisation is the birth right of every child. As many parents are adopting a small family norm, it is our duty to ensure that every child is fully immunised. Immunisation is one of the most cost effective health care interventions. All pediatricians must be well versed with the scientific basis of the principles and practice of childhood immunisation. This teaching slide set and the guide book have been specially prepared for you by the Committee on Immunisation of the Indian Academy of Pediatrics.

### HISTORICAL ASPECTS

#### Vaccine Discoveries - Jenner to 20th Century

- **Jenner. Cowpox Vaccination 1796**  
**Pasteur. Rabies prophylaxis 1885**
- **Expanded Programme on Immunisation (EPI)**  
**WHO 1974      INDIA 1978**  
**Six diseases targeted**
- **Universal Immunisation Programme (UIP)**  
**INDIA 1985**  
**Universal coverage targeted 1990**

## **HISTORICAL ASPECTS**

- ◆ **Children's Vaccine Initiative (CVI)**
  - **Summit for children, 1990. CVI 1991**
  - **Newer Vaccines & production technologies**
- ◆ **Global programme on Vaccines (GPV)**  
**WHO 1993 Consolidating achievements**  
**New targets**
  - **Eradicate polio, Eliminate NNT,**  
**Prevent measles mortality**

## **ACHIEVEMENTS**

- ◆ **Smallpox eradicated 1977**
- ◆ **EPI coverage >80% 1990**
- ◆ **Over 3 million lives saved annually**
- ◆ **Preventing blindness, paralysis in 1 million**
- ◆ **Polio targeted for eradication by 2000**

The first documentation of successful cow-pox inoculation (vaccination) to protect against smallpox was established by Edward Jenner in 1796. This pioneering work paved the way for many new vaccine discoveries, as well as the eradication of smallpox itself. The second vaccine was developed by Louis Pasteur, against rabies, for post-exposure prophylaxis. It was first given to a child in 1885. Since then many other vaccines were developed in rapid succession.

At the global level, an organised Immunisation Programme came into existence in the year 1974 under the WHO banner, the 'Expanded Programme on Immunisation' (EPI). The target population were children under 5 years and pregnant women. The vaccines included for children under 5 years were BCG, DPT, OPV and Measles and TT for pregnant women. India adopted EPI in 1978 with Typhoid vaccine replacing Measles vaccine. When the EPI coverage was found to be very low on evaluation, the Universal Immunisation Programme (UIP) was introduced in India in 1985, concentrating on the target population of infants below one year.



The vaccines recommended were BCG, DPT, OPV and Measles for under one year infants and TT for pregnant women. Under UIP, the earlier target of 85% coverage of EPI was removed, so that every infant was now targeted for immunisation. Globally this approach was adopted by the WHO; this is called Universal Childhood Immunisation (UCI). Efforts were being undertaken to initiate research for the development of newer vaccines, to improve vaccine production technologies and to understand the epidemiologies of diseases. These efforts were highlighted in 1990, in the Summit for children, celebrating the success of EPI, achieving the target of 80% coverage, globally with the 6 vaccines. Such efforts were streamlined under the banner Children's Vaccine Initiative (CVI) with support from several international/agencies like WHO, UNICEF, World Bank and the Rockefeller Foundation.

These efforts were further consolidated by the global movement called 'Global Programme on Vaccines and Immunisation' reflecting the EPI and UCI initiatives and combining them with the CVI.

Since the introduction of UIP in India there has been a significant decline in all of the vaccine preventable diseases, such as poliomyelitis, neonatal tetanus, diphtheria, whooping cough, measles and meningeal and miliary tuberculosis.

IAP has always actively supported and associated itself in the National Immunisation efforts since its inception. Indeed our involvement precedes the national programme. IAP has pioneered immunisation efforts as well as the propagation of the messages and the principles and practice of immunisation. This Guide Book is a current expression of our continued efforts.

## **BASIC IMMUNOLOGY**

The Greek word "Immune" means "to be protected". The protection offered by the introduction of various antigens or antibodies is called acquired immunity. The process by which this acquired immunity is obtained is known as 'Immunisation'.

Immunisation is of two types viz active and passive. When specific antigens evoke the needed immune response in the system it is called active immunisation and when antibodies are supplied readymade in the form of immunoglobulins and sera it is known as passive immunisation.

Each and every vaccine is selected based on three important criteria viz., necessity, safety and efficacy. And a vaccine thus selected has already undergone the following three basic trials before it is licensed :

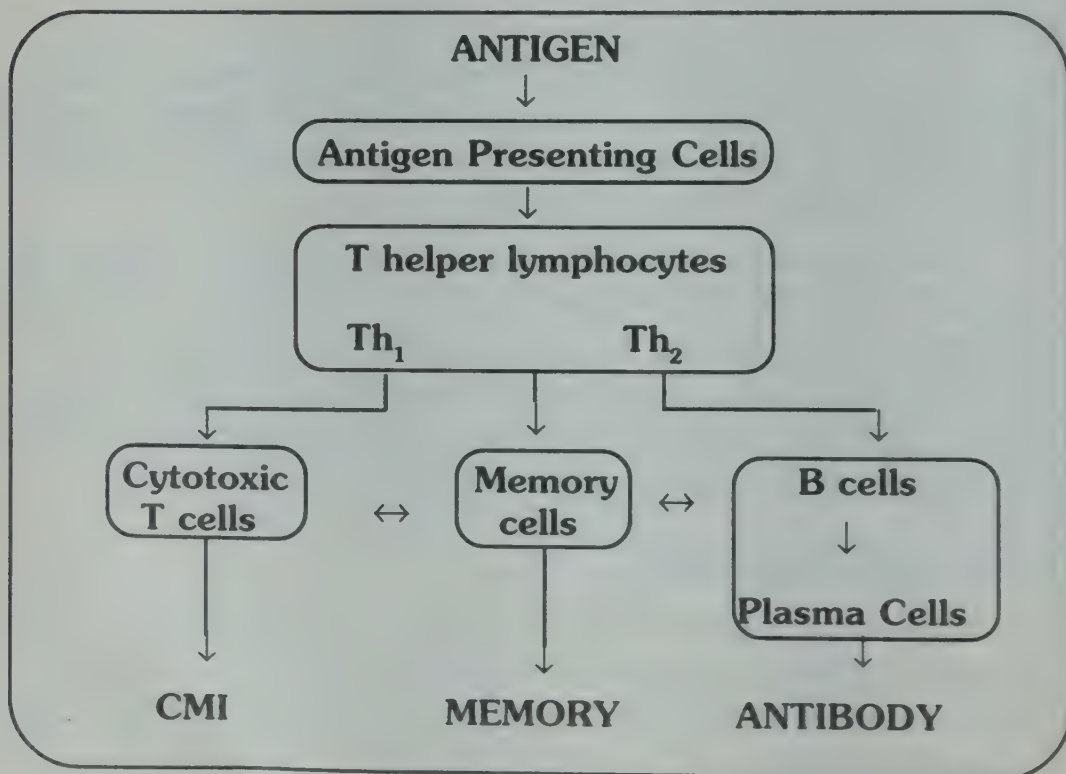
Phase I Trial (Human volunteers, for tolerance, safety)

Phase II Trial (Human volunteers, for immune response, safety)

Phase III Trial (For Field efficacy, safety)

Further, before a vaccine is actually marketed it undergoes the sterility, purity and potency tests at the level of the manufacturer and the National Control Authority.

### BASIC IMMUNOLOGY





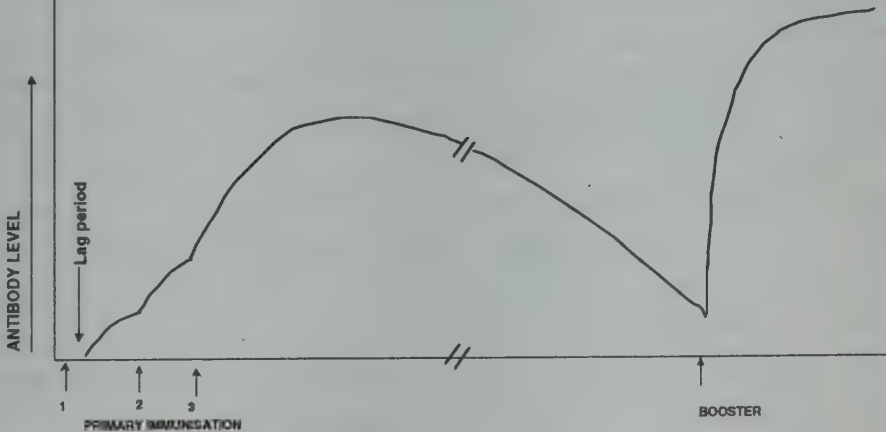
## TYPES OF VACCINES

### Type of antigen

### Example

Live bacteria, attenuated	BCG; Ty21a
Live virus, attenuated	OPV; M,M,R,V
Killed bacteria	Pertussis ; S. typhi
Killed virus	IPV, Rabies, HAV
Toxoid	D, T
Capsular polysaccharide	Vi, Hib, Mening, Pneumo
Viral subunit	HBsAg
Bacterial subunit	Acellular pertussis

### ANTIBODY RESPONSE TO NON-REPLICATING ANTIGEN



The pathogenic infectious agent induces disease and the host immune system responds with immunity, first to ensure recovery and secondly to offer protection from disease if the same pathogen is encountered again. A vaccine is composed of one or more antigens of the pathogen, which will induce protective immune response without the risk of the disease itself.

Vaccines consist of attenuated live organisms (eg. oral polio vaccine, oral typhoid vaccine, injected measles vaccine), whole organisms in a killed form (eg. Pertussis vaccine, whole cell typhoid vaccine, rabies vaccine, killed polio vaccine), modified exotoxins called toxoids (eg. diphtheria toxoid, tetanus toxoid), or subunit vaccine (eg. polysaccharide capsular antigens of ***S. typhi*** or ***Haemophilus influenzae*** type b and the surface proteins of hepatitis B virus).

The vaccine mimics the infection with the respective pathogen, but without risk of the disease. The consequent immune response may be manifested through antibody (humoral immunity) or cell mediated immunity, or both. If the antigen stimulates Th<sub>1</sub> series of T helper lymphocytes, then stronger cytotoxic lymphocytic response is obtained; if Th<sub>2</sub> series is stimulated, the ultimate expression of immunity is predominantly humoral. Carbohydrate antigens are T cell independent; hence they stimulate B cells directly without T helper cell modulation. The result is predominantly IgM response without IgG production or induction of immunological memory. BCG elicits CMI. Maternal CMI is not transferred to the foetus. Therefore BCG can be given at birth, OPV is given by mouth; it establishes local infection in a proportion of children. Maternal antibody in the infant's circulation is a very weak inhibitory factor; hence OPV also can be given at birth. Hepatitis B surface antigen is an excellent immunogen, overcoming, to a large extent, the inhibiting effect of maternal antibody; hence that too can be given at birth. On the other hand, live measles vaccine may be completely inhibited in the presence of detectable maternal antibody in the infants circulation. Therefore measles vaccine is given after a delay of 9 months from birth, and MMR only after 12 months.

To be successful in protective role, vaccines should be given before the age when the infection itself is anticipated. In the case of tetanus, neonatal tetanus cannot be prevented by immunisation of the infant. Therefore high maternal antibody levels are ensured by immunising the pregnant women. The transplacental antibodies protect the neonate.

The currently used childhood vaccines do not have any interference with each other. Therefore they can be given simultaneously. Several antigens can be given the same day. Between any two immunisation sessions, 4 weeks interval is recommended. Between 2 doses of the same vaccine, a minimum interval of 4 weeks should be observed. Increasing the interval between doses to 2 or 3 months actually improves antibody levels. The maximum allowed interval between the first and second dose of a non-live vaccine is arbitrarily one year. Between the 2nd and 3rd dose also, the minimum interval is 4 weeks, the optimum 3 to 6 months and the maximum, again arbitrarily five years.

## **UIP SCHEDULE**

### **UNIVERSAL IMMUNISATION PROGRAM, CHILDHOOD IMMUNISATION SCHEDULE GOVT OF INDIA**

- **BCG** : **Birth or 6 weeks**
- **OPV** : **Birth, 6, 10, 14 weeks  
15-18 months**
- **DPT** : **6, 10, 14 weeks  
15-18 months**
- **MEASLES** : **9 months**
- **DT** : **5 years**
- **TT\*\*** : **10 and 16 years**

**\*\* if given for the first time at this age give 2 doses at 4 weeks interval.**

**\*\* for pregnant mothers 2 doses of TT at 4 weeks interval.**

The World Health Organization (WHO) popularised the concept of routine immunisation of infants under the title of Expanded Program on Immunisation (EPI), launched in 1974.



The Govt. of India adopted EPI in 1978, and renamed it Universal Immunisation Program in 1985. Under UIP, 2 vaccines are recommended at birth. These vaccines, namely BCG and OPV may be given from the day of birth until 2 weeks of age, so that there would be 4 weeks gap until the next contact for immunisation at 6 weeks.

If the opportunity to give BCG was not available in the neonatal period, it may be given at 6 weeks, simultaneous with DPT and OPV.

Each time a dose of a vaccine is given, the doctor should explain to the mother the nature of vaccine, the number of doses needed, the disease to be prevented, adverse reactions and their probability and treatment, and the date due for the next session of immunisation.

We will now consider in detail each vaccine recommended in the UIP Schedule. For convenience these vaccines are called EPI Vaccines.

## **EPI VACCINES**

### **BACILLUS CALMETTE GUERIN (BCG) VACCINE**

- **Attenuated *M. Tuberculosis* var bovis developed in 1921**
- **Protects against TB meningitis, Miliary TB**
- **Maternal antibodies do not interfere with BCG 'take'; CMI not transferred transplacentally**

### **BACILLUS CALMETTE GUERIN (BCG) VACCINE**

- **Supplied freeze dried, Store frozen or refrigerated**
- **Use reconstituted BCG within 4-6 hours**
- **Inject intradermally over left shoulder**
- **Local lesion due to bacterial multiplication; heals leaving scar; If no scar, repeat BCG**

The pathogenesis of tuberculosis and immunity in infected persons are very complex phenomena. Infection with BCG although very localised and with attenuated bovine tubercle bacilli, induces cell mediated immunity and some protection. The protection is maximum against the haematogenous spread of ***M. tuberculosis***, which results in miliary TB or TB meningitis. The vaccine efficacy is in the range of 70-80% protection against these 2 forms of TB but less than 50% against adult (secondary) forms of tuberculosis. BCG can be given to neonates since maternal antibodies do not interfere with BCG 'take'. Indeed antibodies against ***M. tuberculosis*** do not appear to have protective function.

The vaccine is supplied as a lyophilised (freeze-dried) preparation, which is to be reconstituted with the recommended diluent. Sterile distilled water or normal saline may be used for reconstitution. In liquid phase the organisms tend to be temperature-sensitive and the potency may drop with increasing time. Moreover, the vaccine contains no antibacterial substance, hence bacterial contamination may occur with repeated entry into the vial and several hours after reconstitution. Hence once reconstituted, the vaccine should be used within 4-6 hours.

The injection of BCG should be strictly intradermal, using special needle and syringe capable of clearly measuring 0.05 ml and 0.1 ml and delivering such small volumes without loss in the 'dead space' of the syringe nozzle. The convex aspect of the left shoulder is preferred so that inspection for BCG scar may be made easy.

The injected site shows no change for several days. The bacterial multiplication leads to the development of a papule, which often heals after ulceration. The evolution of this lesion, upto healing with scar, may take upto 4 or even 6-8 weeks. The absence of the local lesion, hence, the absence of BCG scar is indicative of unsuccessful vaccination; in that case BCG inoculation may be repeated. Although there is no strict upper age limit for BCG, the most benefit is obtained by inoculation in infancy, the earlier the better.

## ORAL POLIO VACCINE

- **Live attenuated Poliovirus types 1, 2 and 3 developed by SABIN, 1961**
- **Temperature sensitive, store frozen or refrigerated**
- **Can be given simultaneously with any other vaccine**
- **Vaccine virus take = infection of GI tract**

## ORAL POLIO VACCINE

- **Multiple doses necessary to ensure vaccine virus take and antibody response to all 3 types of polioviruses**
- **First dose recommended for newborn, since maternal antibodies do not interfere with vaccine virus take**
- **IAP recommends additional fifth dose of OPV at 9 months and a seventh dose at 5 years**

The oral polio vaccine is a suspension of over 1 million particles of polioviruses types 1, 2 and 3 together. It is supplied with a stabilising agent, namely magnesium chloride. Therefore the potency is quite stable under refrigeration or freezing. Several cycles of freezing and thawing do not reduce the potency. When OPV is given by mouth, the vaccine viruses go through the stomach and reach the intestines where they must establish infection (= vaccine virus take) before an immune response may occur. The viruses survive the acidity of the stomach. However, for reasons not clearly understood, the 'take' rate is relatively low in our children.

For the above reason, multiple doses (atleast 5) of OPV are necessary before 90-95% of children develop immune responses to all 3 poliovirus types. It is for this reason that the IAP recommends 5 doses of OPV in infancy, coinciding with the



already existing 5 contacts for BCG, DPT (3 doses) and measles vaccine. Fortunately, one neonatal dose can be given with response rate no worse (indeed somewhat better) than when given at 6 weeks of age or later.

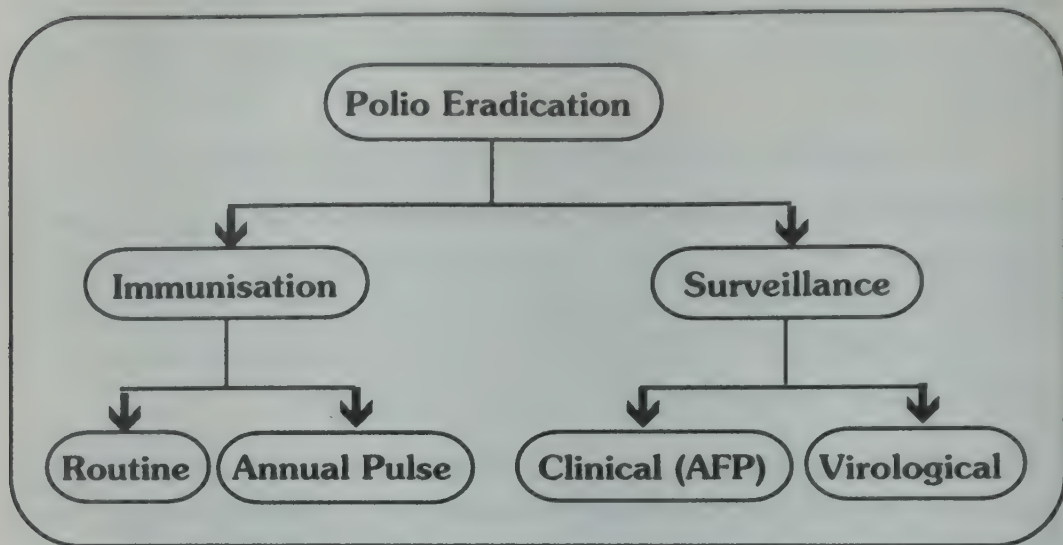
In order to ensure that vaccinated children do not participate in the chain of transmission of wild (pathogenic) polioviruses, a high level of gut immunity should be induced in them. For this reason also multiple doses of OPV are necessary: IAP recommends 2 additional doses simultaneous with booster doses of DPT (during second year of life and at 5 years).

When a large proportion of infants are given 5 doses and a large proportion of preschool children and continued with 2 more doses in preschool age, poliomyelitis will disappear from that community. Moreover 5-7 doses of OPV assures the best probability of individual protection against poliomyelitis.

All member countries of WHO have declared that poliomyelitis should be, and will be eradicated, globally, by the year 2000.

Eradication is defined as the absence of circulation (transmission) of wild polioviruses in any human community. The absence of clinical poliomyelitis is called 'zero polio' status. Since poliovirus can infect children silently, zero polio state does not necessarily mean polio eradication.

## STEPS IN POLIOMYELITIS ERADICATION



- \* Adequate immunisation is the method of eradication.
- \* Clinical surveillance is the method to confirm zero polio status.
- \* Virological investigations are necessary to document eradication.

In developing countries with high (pre-immunisation era) incidence of polio, such as in India, 3 or 4 doses of OPV given to even 90% or more infants, did not result in polio eradication. In such countries either routine immunisation with 5-7 doses of OPV and 90% coverage or annual pulse immunisation (Pulse polio immunisation, PPI) will be necessary to achieve eradication. Surveillance must **detect** all cases of Acute Flaccid Paralysis (AFP), **report** them and **investigate** for poliovirus aetiology. When any poliovirus is detected it should be examined by genomic analysis to identify it as wild poliovirus and to distinguish from vaccine strain of poliovirus.

## DIPHTHERIA, PERTUSSIS, TETANUS VACCINE

- Diphtheria toxoid (Ramon & Glenn, 1923)
- Killed *Bordetella pertussis* (Madsen, 1923)
- Tetanus toxoid (Ramon & Zoeller, 1927)
- Toxoids adjuvanted (Aluminium hydroxide / phosphate)
- DPT vaccine supplied as liquid, store refrigerated
- Aluminium adjuvanted vaccines should not be frozen
- Inject intramuscularly, anterolateral thigh

### DPT VACCINE

- Alert parents about local reaction and fever; Paracetamol may be given to reduce pain / fever
- IAP recommends second booster at 5 years
- H/o convulsions not contraindication
- Progressive neurological disease or serious adverse reaction to earlier dose are contraindications for DPT; replace with DT vaccine

The combination of diphtheria toxoid, whole cell killed pertussis vaccine and tetanus toxoid is popularly known as the triple antigen. While the two toxoids are highly immunogenic and antibodies to them are almost completely protective, the pertussis vaccine, given in 3 doses, has a protective efficacy of about 70-80% only. Moreover, local (pain and redness) and systemic (fever) side-effects of the DPT are almost entirely due to the pertussis component. The whole cell pertussis vaccine was suspected to induce a neurological reaction in very rare instances; however there has been no conclusive proof for this. Convulsions following DPT vaccine are rare, and when they do occur, they may be either quite benign (perhaps induced by high fever), or they may be the earliest signs of some incipient neurological disease in the infant. For these reasons, progressive neurological diseases are the only contraindications to DPT immunisation.

The DPT must be injected intramuscularly and the preferred



site is the anterolateral aspect of the thigh. The gluteus region is better avoided for 2 reasons. Occasionally the needle (and the vaccine itself) hits the sciatic nerve, causing injury, which may result in foot-drop or even more extensive paralysis. Secondly, the vaccine may be deposited in the fat pad adjacent to the muscle tissue; in that case the immune response is likely to be less than what would occur after true IM injection. This phenomenon has been shown to be important in the case of HB vaccine; although not shown directly with DPT, it is better to adhere to the principle of no IM injection gluteally.

How many doses of DPT should a child receive? As far as tetanus is concerned, life-long immunity is necessary. Therefore at least 5 doses are recommended during the preschool age followed by boosters at 10 and 16 years of age. Regarding Diphtheria, no boosters are generally given in our country beyond 5 years. Hence 5 doses are important. The UIP recommends 4 doses of pertussis vaccine - 3 during infancy and the fourth during the second year of life. The need for continued protection against whooping cough in adolescents and adults is increasingly being recognised. Therefore IAP recommends the 5 opportunities available to give 5 doses of pertussis vaccine also. Hence, while UIP recommends DT vaccine at 5 years, IAP recommends DPT vaccine.

## **MEASLES VACCINE**

- **Live attenuated Measles virus vaccine developed by Enders, 1960**
- **Vaccine further attenuated (Eg. Schwarz, Edmonston-Zagreb)**
- **MV supplied freeze dried, Store frozen or refrigerated**
- **Use reconstituted vaccine within 4-6 hours (Refrigerate, do not freeze)**
- **Inject subcutaneously, preferably right upper arm**

## MEASLES VACCINE

- **Recommended age 9 months (270 days) plus**
- **During measles outbreak, may be given at 6 months plus**
- **If given at <9 months, repeat dose after interval of at least 3 months**
- **Alert parents of fever 5-10 days later; Paracetamol may be given**

The measles vaccine consists of live attenuated measles virus, developed by Enders, in 1960. The original virus strain was isolated from a child by the name Edmonston; therefore the virus strain was also named Edmonston. After attenuation it was called Edmonston B; this virus strain was not fully attenuated. Therefore several strains of further attenuated Edmonston B was developed by various investigators. Such strains in use as measles vaccine are Schwarz, Moraten, Edmonston-Zagreb etc. In liquid suspension the vaccine virus is very heat-labile; in the freeze-dried state the shelf-life of the vaccine is one to two years, or even longer. The vaccine may be stored frozen or refrigerated. But, after reconstitution, the vaccine should be injected within 4-6 hours. During such interval the liquid vaccine should be kept cold, either in the refrigerator or vaccine carrier.

The measles vaccine does not contain any antibacterial preservative. Therefore, strict aseptic technique should be used when entering the vial. If the vaccine gets bacterial contamination, bacteria may multiply, especially if liquid vaccine is kept at room temperature or if stored for longer periods. Such negligent practices have led to staphylococcal sepsis/toxic shock syndrome in rare instances. Unused vaccine should, therefore be discarded after 4-6 hours.

The vaccine should be injected subcutaneously. The preferred site is right upper arm; this is only for uniformity. It can also be injected over the anterolateral thigh, but subcutaneously.

The age distribution of natural measles, in unimmunised children, vary from place to place and from time to time. While most infants are protected from measles by the maternal antibodies upto 4-6 months, most infants are susceptible to the disease from 9 months onwards. If measles vaccine is given in the presence of measurable titres of maternal antibody, the vaccine viruses are neutralised and the child does not respond with antibody. In order to achieve the best balance between these competing demands of early protection and high sero conversion, 9 months of age is recommended as the ideal, in our country. 9 months means 270 days or more. In case of an outbreak (or impending outbreak) infants completed 180 days (6 months) may be given the vaccine, provided such infants (given vaccine below 9 months) are revaccinated after at least 3 months of interval.

Being a live attenuated virus vaccine, it results in actual infection and multiplication of viruses within the body. This infection mimics the wild measles virus infection, except, a) the disease measles is either totally absent or may occur in a very mild form and b) the infection does not spread from the vaccinated child to anyone else.

The response to the infection may present as a short fever, of 2-3 days, starting from about 5-10 days after immunisation. We could consider this as the "incubation period", which is shorter by about 4 days than the incubation period of measles itself. In some infants/children, the fever may be high enough to cause febrile convulsions. Some 2-5% of children may have a few spots of rash, visible on fair skin, but often missed on darker skin.

Since the fever is expected, parents should be alerted. The child should be examined if the fever is longer than 3 days or if other symptoms suggestive of an unrelated illness are present. Paracetamol may be given to control/reduce fever.



# TETANUS TOXOID VACCINE

- **IAP recommends TT at 10 & 16 years of age.**
- **For previously unimmunised school age children primary TT immunisation with 2 doses 4 weeks apart.**
- **For previously unimmunised pregnant women give 2 doses of TT at  $\geq 4$  weeks interval; second dose  $\geq 2$  weeks before delivery.**

The reason for TT at 10 and 16 years was given earlier. After completing the full course of 7 doses, there is no need for additional doses during pregnancy, at least for the next 10 years. Thereafter a single booster would be sufficient to extend immunity for another 10 years. For pregnant women who have not had previous immunisation, at least 2 doses should be given during pregnancy so that protective antibody would be transferred to the infant in order to prevent neonatal tetanus.

## IAP RECOMMENDATIONS

- **IAP endorses and supports UIP**
- **For families able to afford cost, IAP recommends**

<b>Additional doses</b>	<b>:</b>	<b>OPV, DPT</b>
<b>Newer vaccines</b>	<b>:</b>	<b>MMR, HB</b>
<b>Optional vaccines</b>	<b>:</b>	<b>Typhoid, Hib</b>

IAP fully supports the UIP and its immunisation schedule, recognising the fact that it provides the basic minimum needs of all children in the country. All the doses are given free to all eligible children. This is a laudable programme which has already achieved great success.

IAP recommends that this schedule can be supplemented with additional doses of the same vaccines, for example OPV and DPT

or with newer vaccines, such as MMR and Hepatitis B vaccines. Having been convinced that there is urgent need to work towards including HB vaccine in the UIP, IAP recommends that all paediatricians (and obstetricians) should counsel families regarding the IAP recommendation.

### **IAP IMMUNISATION TIME TABLE**

<b>Vaccine</b>	<b>Age recommended</b>
<b>BCG</b>	<b>: Birth - 2 weeks</b>
<b>OPV</b>	<b>: Birth, 6, 10, 14 weeks, 9 months 15-18 months, 5 years</b>
<b>HB</b>	<b>: Birth, 6 weeks, 6-9 months, 10 years</b>
<b>DPT</b>	<b>: 6, 10, 14 weeks 15-18 months, 5 years</b>
<b>MEASLES</b>	<b>: 9 months plus</b>
<b>MMR</b>	<b>: 15-18 months</b>
<b>TT</b>	<b>: 10, 16 years</b>

Using the principles described in above, IAP has developed a time table of immunisation. It uses the basic immunisation schedule of the UIP, supplemented with additional doses of the same vaccines as well as with some newer vaccines. The additional doses are for OPV and DPT. For personal protection against paralytic poliomyelitis by avoiding vaccine-failure, IAP recommends 5 doses of OPV during infancy. This fits in well with the five contacts with the infant in UIP, for BCG, DPT and measles vaccines. At each contact, a dose of OPV is recommended. For those infants who were not given one dose of OPV at birth, a fourth dose of OPV can be given 4 weeks or more after the third dose of OPV and DPT. Then the 5th dose will coincide with the measles vaccine. Two more doses of OPV are recommended at 15-18 months and 5 years of life, coinciding with the boosters of DPT. These doses are meant to fill any gaps in polio immunity as

well as to reinforce gut immunity in order to prevent wild virus infection and transmission. These doses are no longer important for those children receiving 2 or more doses of OPV in the annual national OPV pulse immunisation programme.

As pertussis is being recognised occurring in adults, young or old, it is increasingly becoming clear that the protection induced by 3 or 4 doses of pertussis vaccine does not last long enough. It is for this reason that IAP recommends a fifth dose of pertussis vaccine as the second booster with DPT.

In the UIP schedule, BCG and OPV are recommended at birth. IAP defines the time as any day from the day of birth upto 14 days. This limit is set so that there would be a gap of 4 weeks if the second dose of OPV is given at 6 weeks as recommended.

### **HEPATITIS B VACCINE**

- **HBsAg from plasma given to immunise by Krugman, 1976**
- **Vaccine : Plasma derived HBsAg or HBsAg from Genetically Engineered Yeast Cells**
- **Supplied as liquid; aluminium salt adjuvanted**
- **Store refrigerated, not to be frozen**
- **Inject IM, avoid gluteal site**

### **HEPATITIS B VACCINE**

#### **HB IMMUNISATION, FIRST DOSE**

- **If Mother is known carrier :**  
**At birth HBIg & HB vaccine 1 dose or HB vaccine alone**
- **If Mother is known non-carrier :**  
**HB vaccine need not be started at birth**  
**Instead first dose at 6 weeks**
- **If Mother's status not known :**  
**HB vaccine at birth**
- **IAP does not recommend routine testing of mothers**



THE UNIVERSITY OF CHICAGO  
DIVISION OF THE PHYSICAL SCIENCES  
DEPARTMENT OF CHEMISTRY  
530 SOUTH EAST ASIAN AVENUE  
CHICAGO, ILLINOIS 60607-7070

TO THE EDITOR:  
I am writing to you regarding the article  
published in the *Journal of the American Chemical Society*,  
vol. 115, no. 1, p. 100, 1993, by  
J. K. Stille, J. E. McGrath, and J. H. Duerksen.

The article is titled "A New Class of  
Polyimides with High Glass Transition  
Temperatures and High Thermal Stabilities."  
The authors claim that the polyimides  
described in the article have high glass transition  
temperatures and high thermal stabilities.

The authors state that the polyimides  
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We have inadequate data regarding the need of booster doses. Many believe that the primary 3 dose or 4 dose schedule is sufficient for protection against Hepatitis B disease, as well as against the development of HBsAg carrier state if infected with HBV, for the entire childhood and adolescence period. However, such vaccinees may become susceptible to silent HBV infections which can be detected by the development of antibodies to HBV core antigen (Anti HBc).

The IAP has recommended one booster dose of HB vaccine at 10 years of age in order to boost the antibody levels and hence the degree of protection during adult age, especially the sexually active age. Earlier, a booster had been suggested even at 5 years of age: this is considered to be unnecessary.

## **RUBELLA AND MUMPS VACCINES**

- **Live attenuated Rubella vaccine, developed by Weller, 1962**
- **Live attenuated Mumps vaccine, developed by Hilleman, 1966**
- **Supplied as Rubella(R), Mumps-Rubella (MR) or Measles-Mumps-Rubella (MMR) vaccines**
- **IAP recommends Rubella and Mumps immunisation**

## **PREVENTION OF CONGENITAL RUBELLA**

- **Selective Rubella immunisation of adolescent girls**
- **Selective Rubella immunisation of pre-school and adolescent girls**
- **Universal immunisation of pre-school boys and girls**
- **Combination of the above.**



Mumps and Rubella vaccines also consist of live attenuated viruses. From a national public health point of view these vaccines have much lower priority than that of measles vaccine. These two virus infections and their diseases are not associated with significant mortality. However, there is increasing awareness of the occurrence of congenital rubella syndrome, especially in urban and well-to-do families. Therefore IAP recommends rubella immunisation for children in families who can afford to pay the cost. Similarly, to avoid the discomfort and the rare complications of Mumps, mumps vaccine is also similarly recommended.

At the present time IAP recommends a dose of MMR vaccine to all children, where parents pay the cost. For infants given measles vaccine at 9 months, MMR may be given after completing 12 months. If measles vaccine is given later, a 3 months gap is advisable. If measles vaccine was missed altogether, one MMR dose replaces it, when given at or after 12 months.

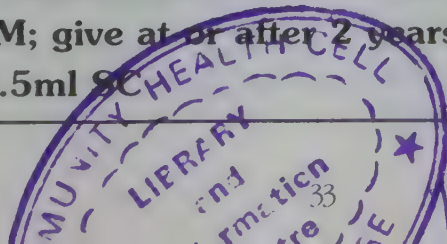
## OPTIONAL VACCINES

### TYPHOID VACCINE

- Killed *S. typhi*, often with *S. paratyphi* A (TA)
- Developed by Wright, 1896
- Liquid, store refrigerated, inject subcutaneously
- Primary course : 2 doses 4 weeks apart 6-9 months of age or at any age
- Boosters : Once in 3-5 years
- Dose : 0.5 ml SC or 0.1 ml ID

### TYPHOID VACCINE

- Vi polysaccharide, developed by Robbins, 1984
- Liquid, adjuvanted, store refrigerated
- Inject IM; give at or after 2 years
- Dose 0.5ml SC



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## TYPHOID VACCINE

- Live attenuated *S.typhi*, developed by Germanier, 1975
- Strain name : Ty 21 a
- Enteric coated capsules : store refrigerated give orally on 3 alternate days
- May be repeated 3-5 years later
- Recommended age : 6 years and above

Typhoid fever is widely prevalent in India and 3 good vaccines are available. IAP does not recommend any of the vaccines universally but paediatricians should assess the local epidemiology of typhoid fever and offer immunisation when necessary. The choice of vaccine is also a matter of discretion/option between the parents and the doctor.

The heat-killed, phenol-preserved, whole cell ***Salmonella typhi*** vaccine was developed one century ago. Although IAP would prefer a vaccine containing only ***S.typhi***, most vaccines available in India contains ***S. paratyphi A*** also, thereby increasing the total quantity of killed bacterial cells. This vaccine is not liked by many countries because of the local pain and inflammation and systemic malaise and fever it induces in a large proportion of vaccinees. The bacterial cell wall contain endotoxin, which is the main reason for the reactogenicity. A pure ***S. typhi*** vaccine is less reactogenic than the combined TA vaccine. This typhoid vaccine is extremely safe from serious reactions and is reasonably effective - indeed all typhoid vaccines have comparable efficacy.

The vaccine appears to be protective through the induction of antibodies against cell wall somatic O antigens and the flagellar H antigens. Infants from 6-9 months upward respond to the vaccine with excellent antibody production. The dose of vaccine for children may vary slightly from manufacturer to manufacture, some recommending 0.25 ml and others 0.5 ml. Primary course requires 2 doses, 4 or more weeks apart, given subcutaneously. Boosters need not be given subcutaneously : 0.1 ml given intradermally are as effective as the full dose (0.5 ml) given SC and cause significantly less local/systemic side effect.

This vaccine is extremely cheap and well suited for giving to children of families who cannot afford more expensive vaccines.

The Vi polysaccharide, purified and adjuvanted is another satisfactory typhoid vaccine, with reasonable efficacy and extremely low reactogenicity. As polysaccharide antigens are T cell independent, this vaccine is a) non-immunogenic below 2 years of age b) induces IgM response without IgG response c) not able to induce immunological memory; hence not able to induce booster effect. When a dose is repeated 3-5 years later, it induces response similar to the first dose. This is the more expensive of the two newer typhoid vaccines available today.

The live attenuated strain of *S.typhi*, namely Ty21a, is genetically stable, and does not revert to virulence. Indeed it does not induce a true "infection" as only very limited multiplication occurs in the gastrointestinal tract after oral feeding. It is not excreted in large numbers and is non-transmissible under natural conditions. Very large number of bacteria are necessary as oral doses in order to achieve sufficient degree of local immunity, which is the main basis of protection afforded by this vaccine.

The bacteria are acid-labile. Hence the stomach acidity has to be either neutralised or by-passed when Ty21a is fed orally. That is the reason why it is supplied in enteric coated capsules. This presentation must not be tampered with when immunising children. The age of immunisation is 6 years and above, partly since the capsules are large and not well tolerated by preschool children and partly due to lack of sufficient data in younger children.

The vaccine is to be given in three sittings, on alternate days. This entire course is one dose of immunisation. The protective efficacy is as good as, or perhaps slightly better and also longer lasting than the other two vaccines. Immunisation may be repeated 5 to 6 years later.



## HAEMOPHILUS INFLUENZAE TYPE b VACCINE

- **H. influenzae b capsular polysaccharide**
- **Conjugated to protein antigens to improve immunogenicity**
- **Protein antigen may be TT, DT, Mening OMP etc.**
- **Monovalent or DPT-Hib conjugate**
- **3 doses 1-2 months apart**
- **Booster at 15-18 months**

*Haemophilus influenzae* type b vaccine is a very effective and very safe vaccine. We do know that Hib is an important pathogen causing meningitis or pneumonia in infants and children below 2-3 years. Several conjugated polysaccharide vaccines are available in the world market. As soon as such vaccine(s) become available in India, it may be used as an optional vaccine.

## JAPANESE ENCEPHALITIS AND MENINGOCOCCAL A+C VACCINES

Although the Central Research Institute, Kasauli, a Public Sector vaccine manufacturing unit produces some 2 million doses of JE vaccine; it is not currently available to private sector. If available through local/state Health agencies, or if available through importation, the choice to immunise is left to the paediatricians, after evaluating the local need. This principle also applies for meningococcal vaccine.

## NEWER VACCINES

- **Vaccines already in use in other countries**
  - **Live attenuated Varicella (Oka) vaccine**
  - **Killed virus Hepatitis A vaccine**
- **Epidemiological need in India is under consideration**

## VACCINES UNDER DEVELOPMENT

- **Conjugated Pneumococcal vaccine**
- **Conjugated *S.typhi* Vi vaccine**
- **Rotavirus vaccines**
- **Respiratory Syncytial virus vaccine**
- **Dengue virus types 1-4 vaccine**
- **Vaccines against ETEC, Cholera**

This guidebook describes in detail vaccines that IAP recommends for current use. There are two other vaccines that have recently been introduced in some countries. They are live attenuated Varicella vaccine, and killed Hepatitis A virus vaccine. At the present time IAP committee on immunisation does not consider these vaccines for use in our country. However, both are excellent vaccines - highly efficacious and very safe. The committee will be considering these vaccines shortly, to assess their need in India.

Vaccines that are under active development include pneumococcal polysaccharide protein conjugate vaccines, live attenuated rota virus vaccine, live attenuated dengue virus vaccines and live attenuated and subunit vaccines against respiratory syncytial virus disease. Vaccines against Shigella dysentery, **E.coli** diarrhoea, etc. are under various levels of active research towards development.

## ADVERSE EFFECTS FOLLOWING IMMUNISATION (AEFI)

- **Local reactions**
- **Systemic reactions**
- **Management Guidelines**
- **Reporting to Local Health Authorities**

Although every vaccine passes through purity and sterility tests, some reaction either inherent to the vaccine or as a sequel to its administration may occur rarely. Such reactions are now known as adverse events following immunisation or AEFI for short.

These events can broadly be classified as local reaction and systemic reaction or jointly called 'Adverse Events Following Immunisation' (AEFI).

Inherent reaction are purely temporary and pass off without any permanent sequelae. However adverse events need specific interventions especially so when they are life threatening.

Although the adverse events are rare, every doctor who is dealing with an immunisation procedure, should be prepared to manage these rare events when they occur. Hence it is mandatory for every immunisation clinic to have an emergency set up ready to tackle such post immunisation events.

It is only with this intention a brief account is given in this section delineating the common reactions with a note on their management guidelines.



## ADVERSE EVENTS FOLLOWING IMMUNISATION

S.No	Adverse Event	Vaccine	Symptoms	Management
(1)	Anaphylaxis	Any vaccine	<p>Within minutes</p> <ul style="list-style-type: none"> <li>* Acute decompensation of circulatory system</li> <li>* Hypovolemic shock</li> <li>* Altered sensorium</li> <li>* Laryngo spasm/oedema</li> <li>* Acute respiratory distress</li> </ul>	<ul style="list-style-type: none"> <li>* Adrenaline</li> <li>* Cardiopulmonary resuscitation</li> <li>* IV volume expanders</li> <li>* Oxygen</li> <li>* Dopamine/Doputamine</li> </ul>
(2)	Hypotensive – hyporesponsive episode	DPT	<p>Within 12 hours</p> <ul style="list-style-type: none"> <li>* Acute paleness</li> <li>* Transient decreased level or loss of consciousness</li> <li>decrease or loss of muscle tone</li> </ul>	<ul style="list-style-type: none"> <li>* IV fluids</li> <li>* Dexamethasone</li> <li>* Oxygen</li> </ul>
(3)	Incessant Cry	DPT	<ul style="list-style-type: none"> <li>* Within 48 to 72 hours after DPT immunisation</li> <li>* Excessive inconsolable crying</li> </ul>	<ul style="list-style-type: none"> <li>* Sedation of little help</li> <li>* Feeding advice</li> <li>* Avoid DPT for subsequent dose/s</li> </ul>

S.No	Adverse Event	Vaccine	Symptoms	Management
(4)	Toxic Shock Syndrome	Contamination of Measles vaccine by Staph. aureus	<p>within 30 minutes to few hours</p> <ul style="list-style-type: none"> <li>* Mounting fever</li> <li>* Vomiting</li> <li>* Diarrhoea</li> <li>* Septic Shock</li> </ul>	<ul style="list-style-type: none"> <li>* IV fluids</li> <li>* Antimicrobials</li> <li>* Steroids</li> <li>* Antipyretics</li> <li>* Supportive therapy</li> </ul>
(5)	Lymphadenitis	BCG	<p>Within 2 to 6 months</p> <ul style="list-style-type: none"> <li>* Firm to soft axillary lymphadenitis 1.5 to 3 cms size with or without sinus</li> </ul>	<ul style="list-style-type: none"> <li>* If firm no treatment</li> <li>* If soft and fluctuant HR 9, aspiration if need be</li> <li>* If sinus present steroid therapy</li> </ul>
(6)	Bacterial abscess	Any vaccine	Within 72 hours fluctuant or firm abscess with or without fever	<ul style="list-style-type: none"> <li>* Antibiotics</li> <li>* Antipyretics</li> <li>* Drainage (if need be)</li> </ul>

S.No	Adverse Event	Vaccine	Symptoms	Management
(7)	Sterile abscess	DPT, DT, TT, Typhoid and HB	By 72 hours * Minimum inflammation * No fever	* Drainage if need be
(8)	Moderate local reaction	Any vaccine	Non fluctuant swelling/redness approx., 3cm to 10 cm in size at the injection site	* Paracetamol
(9)	Severe local reaction	Any vaccine	Non fluctuant swelling/redness 10 cm size or larger at the site of injection.	* Paracetamol
(10)	Seizure/s with fever (rare)	DPT Measles	Always generalised simple or complex	* Anticonvulsants * Antipyretics * IV fluids if need be



## COLD CHAIN FOR VACCINES

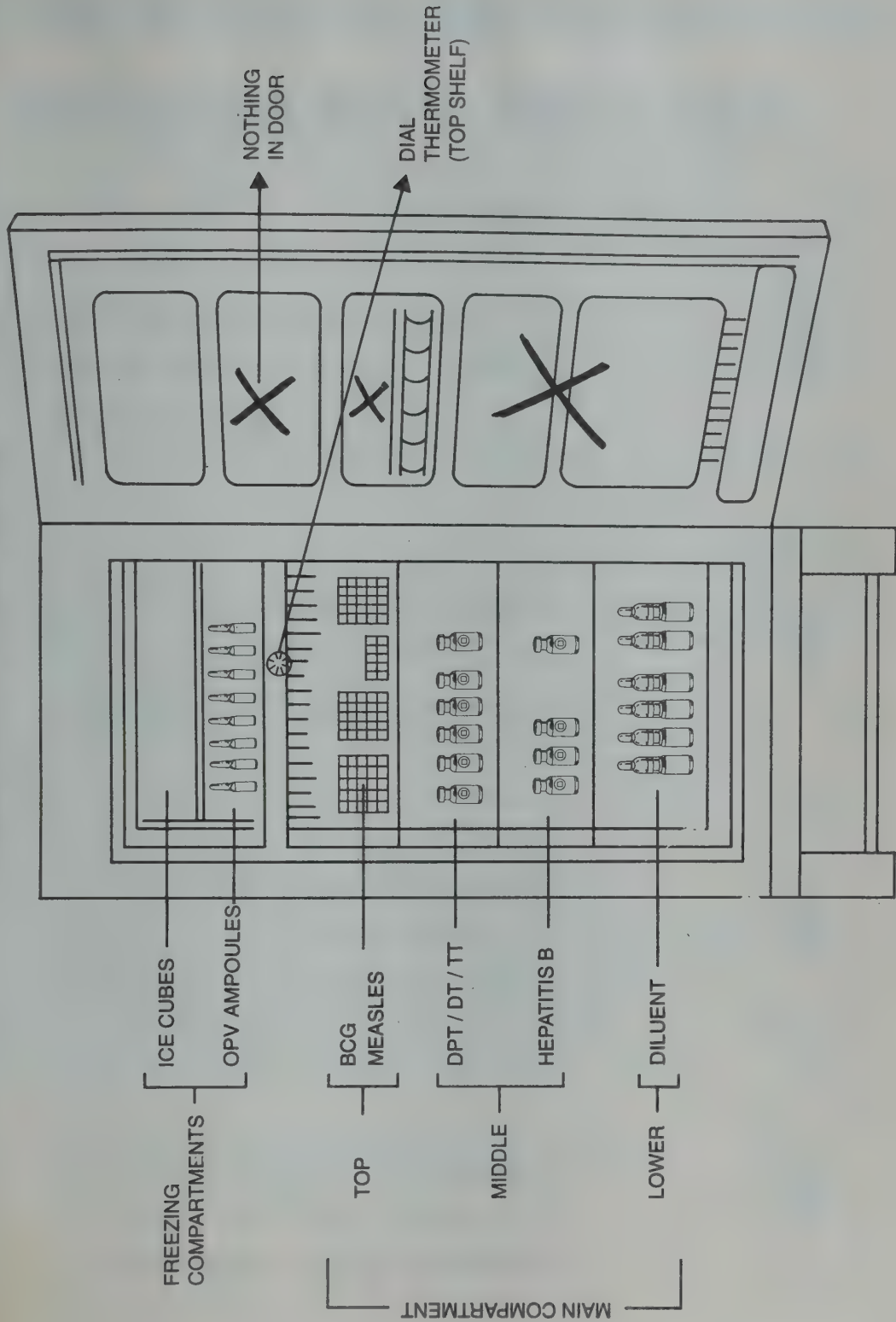
- **The safe zone for vaccine storage + 2° C to + 8° C**
- **Do Not freeze DPT, DT, TT, Typhoid Vi and HB vaccines**
- **Refrigerator / ILR / Deep Freezer used for vaccine storage**
- **Temperature Monitoring**
- **Vaccine Vial Monitor**
- **Potency test for OPV**

Cold chain is the vital link in Immunisation. However, potent a vaccine may be, if cold chain is not maintained from the source of vaccine manufacture to the site of vaccine administration- the vaccine efficacy will grossly suffer. To maintain the potency of the vaccine a safe zone of temperature is mandatory.

The safe zone for vaccine storage for short term i.e. 1 to 2 months is +2° C to +8° C. For long term storage, -20° C is preferred only for BCG, OPV and Measles / MMR. Do not freeze other vaccines. Domestic refrigerators, Ice lined refrigerators are used for short term storage and deep freezer for long term storage. Vaccine carriers are used for carrying the vaccine to an outreach centre which maintain the ideal temperature of +2° C to +8° C with the help of 4 fully frozen ice packs contained in them. Cold boxes are used in fixed centres as alternative vaccine storage equipment in the event of short duration of electricity failures.

Dial Thermometers are used to monitor the ILR temperature and Alcohol stem thermometer for the deep freezer. The temperature monitoring should be done twice a day in the case of ILRs and deep freezers, 24 hours in the walk-in coolers where vaccines are stored in the regional stores for longer period. Currently Vaccine Vial Monitor (VVM) is also available for temperature monitoring.

# REFRIGERATOR SHOWING VACCINES STORED CORRECTLY IN CLINIC SETUP



# Vaccine Vial Monitor

**VVM says....**



The square is lighter than the circle.  
If the expiry date is not  
passed, **use the vaccine.**



The square is lighter than the circle.  
If the expiry date is not  
passed, **use the vaccine.**



The square matches the circle.  
**Do not** use the vaccine.  
**Inform your supervisor.**



The square is darker than the circle.  
**Do not** use the vaccine.  
**Inform your supervisor.**



The T series of vaccines namely DPT, DT, TT, Typhoid Vi cps and also Hepatitis B vaccines should not be frozen. Once frozen the aluminium salts which are used as adjuvants will get desiccated and act as irritants which may result in sterile abscess. Hence, care should be taken not to allow these vaccines to come in direct contact with ice. It is mandatory that shake test is done before the use of either single or multidose vials of these vaccines to make sure that the solution is uniform. Generally, potency of the vaccine stored is tested by lifting a sample vial of OPV only. If this most thermolabile vaccine is found to be potent, the rest of the vaccine are presumed to be equally potent.

If you are storing vaccines in a domestic refrigerator, it should be used only for vaccine storage. You can keep OPV in the freezer compartment and the rest of the vaccines in the non-freezing lower compartments. No vaccine should be stored in the baffle tray or the door compartments. Repeated thawing of OPV should be avoided for all practical purposes. Never carry vaccines in a flask for an outreach place.

All vaccines are available free of cost from your local health authority. You are allowed to collect your professional fees for the services rendered. However, utilisation report should be submitted periodically. You can also send OPV vial for potency test with the help of your local Health Authority.

It is advisable and preferable to adopt a single day immunisation practice in your Clinic / Nursing Home especially when you are using the multidose vials to minimise the risk/s of contamination or potency loss. Alternatively two days a week strategy can be adopted so that the wastage of multidose vials could be avoided.

## VPD SURVEILLANCE

- **Definition and need for surveillance**
- **Importance of AFP surveillance**
- **Objectives for 2000 A.D.**
  - **Polio eradication**
  - **NNT elimination**
  - **Measles - Eliminate mortality**

## VPD SURVEILLANCE

- **Role of professional bodies**
- **Rapport with local health authorities**
- **Immunisation coverage and surveillance**
- **Prediction of seasonal trends and epidemics**
- **Future prospects in surveillance**

Surveillance is a French word which means 'watching with attention, suspicion and authority'. Any satisfactory immunisation programme should result in gradual decline of the vaccine preventable diseases concerned. The WHO has declared 3 distinct objectives for the year 2000 A.D.:

- (1) Polio Eradication
- (2) NNT Elimination
- (3) Measles Reduction.

The 3 different diseases have 3 different nomenclatures in their control because it is possible to eradicate poliovirus from the Globe, but it is not possible to eradicate the source of tetanus bacilli which is animal excreta and spores in the soil. However, by immunising large number of all mothers with TT it is possible to eliminate neonatal tetanus. Although measles can be eradicated in the future, at the present time the single dose measles immunisation

can only prevent measles mortality by preventing measles in the vast majority of immunised children.

Polio eradication consists of 4 stages namely : endemic, control, elimination and eradication. When there is a spurt of polio cases in the months between July to October, the disease is said to be endemic in that particular geographic area. Similarly, if either an alternate year or once in 4 years epidemic pattern is seen, it denotes only a controlled stage. When there is zero reporting for one year, it is called Elimination; and if the zero reporting is for 3 consecutive years it is known as Eradication. However, in the case of neonatal tetanus even with elimination there will be one case for every 10,000 births. In the case of measles there will be considerable reduction in cases as well as deaths due to complications when over 90% measles vaccination coverage is reported. Acute Flaccid Paralysis (AFP) surveillance should be taken on a war footing and all professional bodies and its members should report in the case of AFP to the local Health Authority.

IAP is committed to this cause, and have since founded a National IAP surveillance committee with state and district level co-ordinators.

All cases of vaccine preventable diseases should be reported to the local Health Authority within 48-72 hours for taking prompt field level action. Departments of pediatrics in medical colleges should act as sentinel centres and co-ordinate periodically with the Health Authorities concerned.

IAP is planning extensive research in VPD surveillance in collaboration with the Govt. of India, UNICEF and WHO where your active co-operation at your city/district/state level will be solicited from time to time. The achievement of the goals and objectives of 2000 A.D. largely depends upon an effective surveillance network not only by the Govt. agencies but also by professional bodies like ours wherein each and every one of us will be playing a pivotal role.



## **TOWARDS 21ST CENTURY**

- **More antigens will be in use**
- **Vaccines to be included in UIP**  
**Hepatitis B**  
**Mumps**  
**Rubella**
- **Vaccines to be evaluated for use**  
**Hib**  
**Varicella**  
**Hepatitis A**

## **TOWARDS 21ST CENTURY**

- **Vaccines anticipated against :**  
**Rotavirus, ETEC, Cholera, Shigella.**  
**Respiratory Syncytial Virus**  
**Dengue 1, 2, 3, 4**  
**Pneumococcus**
- **Newer systems of vaccine / delivery**  
**Vector Vaccines**  
**Naked DNA Vaccines**

One thing we can be sure of, that is, we will be giving more antigens, not less, in the next century. In addition to the core of 6 antigens, we now recommend 3 more antigens for routine use - namely Mumps, Rubella and Hepatitis B antigens. Optional vaccines include H. influenzae b and Typhoid; other vaccine included in the UIP are Japanese encephalitis and Meningococcal. We do hope that Hib vaccine will become routine, along with mumps, rubella and HB vaccines, in early 21st century. We anticipate that Varicella vaccine and Hepatitis A virus vaccine also will be widely used.

Research is currently going on for the development of vaccines against Shigella and E.coli.

There is cautious optimism regarding the possibility of developing one or more vaccines against HIV infection or disease. The latter might be a "therapeutic" vaccine to retard the progression of HIV infection to AIDS. For Hepatitis B virus carriers also, there is the need for 'therapeutic' vaccines to retard the progression towards chronic liver disease.

We anticipate vaccines against several serotypes of pneumococci and group A Streptococci, to be in routine use in the early years of the next century. Newer types of vaccines/vaccine delivery systems may also be expected. They include vector-based vaccines and plasmid (naked DNA) vaccines.

## **KNOW YOUR VACCINES**

Though each and every vaccine is discussed individually under the various headings viz., EPI vaccines, Optional vaccines and Future vaccines a "Ready Reckoner" has been given in the following table.

This synopsis will give an idea about the name and contents of the vaccine, type of preparation, age of initiation, schedule, booster, when recommended, dose/s, route and site, instructions to the mother, protective efficacy, contraindications, side effects, storage temperature, associations and incompatibility.

Though this table has been updated as per the available informations, whenever changes are effected subsequently by agencies like the World Health Organisation (WHO), The Government of India (GOI) and Indian Academy of Pediatrics (IAP), you are requested to refer the latest recommendations and act accordingly.

Similarly, the IAP Immunisation and Health record has also been designed incorporating the currently available vaccines, there will be scope for future vaccines whenever they are licensed for use in India.

# KNOW YOUR VACCINES

Vaccine		Type of prepa- ration	Age of initiation	Sched- ule	Booster	Dose
Name	Contents					
1	2	3	4	5	6	7
B.C.G. live attenuated vaccine (LAV)	Bacillus Calmette Guerin strain of bovine mycobacterium tuberculosis 0.1 to 0.4 million viable bacteria per dose.	Lyo- philised	Earliest after birth or at first contact	Single dose	Not given routinely.	0.05 ml newborns 0.1 ml for infants and children
DPT	Diphtheria Toxoid 25 lf Tentanus Toxoid 5 lf Pertussis 4 IU (20,000 million killed bacteria)	Liquid	6 wks	3 doses 6,10, 14 wks.	15-18 months, 5 yrs.	0.5 ml.
OPV (LAV)	Attenuated Polio virus (Sabin) strain Con./dose Type-I:10 <sup>6</sup> TCID-50 Type-II:10 <sup>5</sup> TCID-50 Type-III:10 <sup>5.5</sup> TCID-50	Liquid	Birth	Birth, 6, 10, 14 wks, 9 mts	15-18 months, 5yrs	2 drops
Hepatitis-B	1. Recom binant DNA vaccine 10 mcg/dose (SmithKline Beecham) 2. Plasma derived vaccine 5/10 mcg/dose	Liquid	At Birth within 48 hr or all ages.	3 doses Newborns Birth, 6 weeks, 6-9 mts. Infants and children 6, 10 wks, 6-9 mts. Others 0, 1mt, 6mt.	Booster at 10 years	0.5 ml (10 mcg.)



Route and site	Protective efficacy	Contra-indications	Side effects	Storage Temp. Deg.C
8	9	10	11	12
Intradermal Left Deltoid Do not use antiseptic for local preparation.	0 - 80%	Immune deficiency	Axillary adenitis	+2 - +8°
IM lateral aspect of thigh	Pertussis 80% Diphtheria 80% Tetanus 100%	Progressive neurological disease. Uncontrolled convulsion Severe reaction following first dose	Fever- local pain	+2 - +8°
Oral	80-90% compromised AIDS	Immuno-	None	+2 - +8°
I.M. deltoid muscle	90%	None	Local pain and erythema	+2 - +8°



1	2	3	4	5	6	7
Measles (LAV)	1000 TCID-50 measles virus Schwarz or Edmonston- Zagreb strain	Lyophi- lised	9 mts. (270 days plus)	9-12 mt. 1 dose, 2 dose if 1st dose given before 9 mts. after an interval of > 3 mts.	Nil at present	0.5 ml
MMR (LAV)	Measles as above, Mumps 5000 TCID-50 Urabe AM-9, 1000 TCID-50 Rubella (Wistar RA/3M) cultured on Human diploid cells.	Lyophi- lised	15 mts.	Single dose	Nil at present	0.5 ml.
Mumps (LAV)	Urabe AM-9 5000 TCID-50	Lyophi- lised	15 mts. with Measles and Rubella	Single dose	Nil at present	0.5 ml.
Rubella (LAV)	RA/3M cultured on human diploid cells 1000 TCID-50	Lyophi- lised	15 mts with Measles and Rubella or at 11 yrs.	Single dose	Nil at present	0.5 ml.
Typhoid Heat and Acetone killed or Phenol killed.	S.typhi 1000 million killed organisms per ml.	Liquid	5 yr. can be started at 2 yrs.	2 doses 4 wks. apart.	Every 3 yrs.	0.25 ml less than 10 yrs 0.5 ml more than 10 yrs.

8	9	10	11	12
S.C. Deltoid	95%	Immuno compromised host	Fever Rash after 7 days	+2° - +8°, after reconsti- tution use within 4-6 hours
S.C. Deltoid	95%	Immuno compromised host anaphylaxis following egg allergy pregnancy	Same as in Measles	+2° - +8° after reconsti- tution use immediately
SC Deltoid	90-95%	Immuno- deficiency	Fever	+2° - +8°
SC Deltoid	95-100%	Immune deficiency Rubella recent injection of Gammaglobulin	Fever Arthralgia Adenopathy	+2° - +8°
S.C. Deltoid	57-75% phenol killed. 70-95% acetone killed	None	Fever local pain induration	+2° - +8° Do not freeze



1	2	3	4	5	6	7
Typhoid TY21a	S. typhi 1-3 x 10 viable vaccine organisms per dose	Capsule	6 yrs and above	3 doses alter- nate days.	Every 3 yrs.	1 Cap./ dose
Typhoid Vi Antigen	Vi antigen capsular poly- saccharide 0.25 mcg.	Liquid	5 yr. can be given at 2 yr.	1 dose	Repeat after 5 yr.	0.5 ml.
H infl b PRPD or PRPT or HOC or Tetra Immune with DPT	H. influe- nza capsular polysac- charide-b. 10 mcg.	Liquid	2 mts. if combined with DPT	3 doses after mts. interval if PRPD- after 2 yrs.	1 yr.  3rd dose	0.5 ml.
Meningococcal A+C	Neisseria meningitidis group A, C each 50 mcg.	Lyophilised	not for routine use only in endemic region during epidemics 2 yrs. and above	Single dose	5 years	0.5 ml.
Japanese encephalitis killed Monovalent.	1. Mouse brain Nakayamia NIH strain 2. Baby Hamster kidney P-3, J.E. virus formalin inactivated 7.5-10 LD50/0.30ml. 3. Recombi. DNA vaccine.	Freeze dried or Liquid	Same as in Meningo	2 doses 1 to 2 weeks or one month interval	After 3-4 yrs.	1 ml.
Hepatitis-A Inacti- vated vaccine	HM 175 HAV 17mg of HAV Antigen/ml.	Liquid	Any age	Single or 2-4 doses depending upon the preparation	Nil at present	1 ml.

8	9	10	11	12
Oral	70-80%	Concurrent Abdominal therapy with drugs sensitive to <i>S. typhi</i>	Diarrhoea  Pain Vomiting	+2 - +8°
S.C./I.M. Deltoid/ Anterolateral thigh	70-80%	None	Mild local pain Low grade fever	+2 - +8°
S.C./I.M. Deltoid/ Anterolateral thigh	90-100%	None	Local reaction mild fever	+2 - +8°
S.C./I.M. Deltoid/ Anterolateral thigh	90-95%	None	Mild fever local pain	+2 - +8°
S.C. Deltoid/ Anterolateral thigh	60-80% initially. 100% after Booster	Local redness swelling fever malaise	Pregnancy	+2 - +8°
I.M. Anterolateral thigh	99%	Mild reaction	None	+2 - +8°

1	2	3	4	5	6	7
Varicella vaccine (LAV )	OKA strain Varicella Zoster virus	Lyophilised	1yr or older	Single dose	Nil at present	0.5 ml.
Pneumo coccal	Capsular poly-saccharide	Lyophilised	After 2 yrs.	Single dose	Early 5 yrs	0.5ml.
Rabies (Tissue Culture) Inactivated	(a) HDCV Rabies virus grown in human diploid fibroblasts. (b) PCEC-Rabies virus grown in chick embryo cells. (c) VERORAB Rabies virus grown in Vero cells.	Lyophilised	Any age or after dog bite	<u>Pre expo.</u> Day 0, 7,28 or Day 0, 28, 56 <u>Post expo.</u> Day 0,3, 7,14,30, 3 mt. (Opt) <u>Re expo.</u> within 5 yrs. 2 doses. Day 0 & 7 <u>Re expo.</u> after 5 yrs. Full course of 5 inj.	1st after 1 yr. & then every 3 yrs	0.5 ml or 1.0 ml. depending upon preparation 2.5 IU



8	9	10	11	12
S.C./IM Anterolateral thigh	95-100%	Varicella type rash After 1 week fever	None	+2 - +8°
S.C./I.M. Anterolateral thigh	85-90%	Anti pneumococcal vaccine within last 3 yrs.	None	+2 - +8°
S.C./IM Deltoid Anterolateral thigh	90-100%	None	Local pain, encephalopathy rare	+2 - +8°

## NOTES

# NOTES



## NOTES

# **IAP COMMITTEE ON IMMUNISATION**

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# **IAP Guide Book on Immunisation 1996**

**Committee on Immunisation**

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As an educational grant from:



**SmithKline Beecham**  
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Leading the way in vaccines